UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,243	10/27/2003	Stephen Hamilton	GFI/109 CIP	4492

7590 12/29/2005

James F. Haley, Jr., Esq.
c/o FISH & NEAVE
1251 Avenue of the Americas
New York, NY 10020-1104

EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,243	HAMILTON, STEPHEN	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Applicant's election with traverse of Group V in the reply filed on 6/17/05 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the examiner to examine all the groups because the endomannosidase activity recited in the elected methods is encoded by the nucleic acids and polypeptides of Groups 1-V. This is not found persuasive because the nucleic acids, polypeptides and fusion proteins have other uses besides the elected method of modifying the glycosylation structures of eukaryotic cells. For example, the nucleic acids can be used in a method of detecting the presence of endomannosidase genes in tissue samples or in a method of identifying endomannosidase genes in other organisms. A search of the additional inventions would be burdensome as a search of each of the non-elected inventions would not be coextensive with a search of the others. For example, a search of the claimed nucleic acid sequences would not be coextensive with a search of the polypeptide sequences. Also, the cancellation of all claims reading on the non-elected inventions renders the restriction arguments moot.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method for modifying glycosylation structures on proteins expressed in a eukaryotic host cell comprising: expressing a recombinant nucleic acid encoding an endomannosidase activity that is targeted to a vesicular compartment within the host cell. Applicant also claims eukaryotic cells in a product by process context wherein the cell produces glycosylation structures on proteins as a result of expression of the endomannosidase activity. The claims read on a genus of recombinant nucleic acids encoding any endomannosidase activity that is targeted to any vesicular compartment within the host cell used in the recited methods and host cells containing said recombinant nucleic acids. Applicant also recites use of fragments of at least 60 contiguous nucleic acids of SEQ ID NO:s 1 and 3 that encodes a protein with endomannosidase activity, nucleic acid sequences at least 78% identical to SEQ ID NO: 1 and 3, etc. The prior art discloses a single species (a rat endomannosidase nucleic acid and protein sequence) and applicant discloses putative human, mouse and another rat endomannosidase. The specification satisfies the written description requirement for these specific, disclosed, endomannosidase encoding sequences.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed

correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the instant case, applicant has not presented a structure function relationship correlating the structure of the endomannosidases and their function. Initially, it is noted that the claims encompass a method for modifying glycosylation structures on any protein expressed in any eukaryotic cell by expressing a recombinant nucleic acid encoding any protein having an "endomannosidase activity". This reads on expression of any variant, mutant, allele, derivative or homolog of an endomannosidase protein from any species or source or a fusion protein comprising a portion comprising a protein (or peptide) having endomannosidase activity.

The different rat, mouse and human endomannosidase proteins are in the range of 82-84% identical at the amino acid level. Applicant postulates that, based upon the sequence conservation between the motif DFQ(K/R)SDRI to the C-terminal of the protein, this region may comprise the catalytic domain or be essential to activity of the protein. However, this region of the recited endomannosidases encompasses about 90% of the entire molecule. Applicant notes that the rat endomannosidase differs from the putative human and mouse endomannosidases by lacking a transmembrane domain which the others share and by having a glycine at position 2 which may be myristoylated as a mechanism for membrane localization. Applicant provides only speculative thoughts about any further correlation between the structure of the endomannosidase protein and it's functions. Also, it is unclear how many different

endomannosidases or enzymes having endomannosidase activity are present in the different tissues of any organism. Given the absence of a disclosed or art recognized correlation between the structure of endomannosidases and their function, given the diversity of the sequences of the disclosed endomannosidases and given the broad scope of the claimed genus of molecules, it must be considered, in the view of the skilled artisan, that the species of endomannosidases disclosed by applicant are not a representative number sufficient to describe the claimed genus.

Claim 26 is objected to because of the following informalities: Claim 29 recites "The method of claims 26..." (emphasis added). The claim should read as "The method of claim 26". Appropriate correction is required.

The claimed invention is free of the art. The prior art teaches the cloning and expression, in *E. coli*, of a recombinant endomannosidase from the rat (Spiro et al., 1997, J. Biol. Chem., Vol. 272, No. 46, pp. 29356-29363) and teaches use of recombinant endomannosidase from the rat to evaluate the processing of *N*-linked oligosaccharides of glycoproteins *in vitro* (Spiro et al., Glycobiology, 2000, Vol. 10, No. 5, pp. 521-529) but does not teach modifying the glycosylation structures in eukaryotic hosts. US Patent 6,069,235 (Davis et al.) teaches a method for carbohydrate engineering of glycoproteins but does not recite use of recombinant endomannosidases in said engineering.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
December 23, 2005

DAVID GUZO
PRIMARY EXAMINER